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10/791,179	03/02/2004	Peter H. Sayet	7047-2	3195

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AKERMAN SENTERFITT  
P.O. BOX 3188  
WEST PALM BEACH, FL 33402-3188

EXAMINER

NEAL, TIMOTHY J

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/791,179

Applicant(s)

SAYET, PETER H.

Examiner

Timothy J. Neal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 44-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group II and Species F in the reply filed on 8/18/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 22-43 have been evaluated on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 22-25, 27, 28, 33-36, 38, and 41-43** are rejected under 35 U.S.C. 102(e) as being anticipated by Chao (US 6,869,438).

Chao discloses:

**22.** A non-invasive stomach stricture device, comprising: a front side member (Fig 3 Item 11); a backside member (Fig 3); a connector for coupling the front side member to the backside member to form a clamp, wherein the clamp is designed to clamp a

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stomach (Fig 3).

**23.** The device according to claim 22, wherein the clamp is designed to have a size and shape suitable for fitting adjacent to the trachea side of the upper quadrant of a stomach for regulating nutrient absorption and caloric intake by reducing the capacity of the stomach (Fig 4).

**24.** The device according to claim 22, wherein the backside member and the front side member include stomach contacting surfaces, the stomach contacting surfaces being free of piercing projections (Fig 3).

**25.** The device according to claim 24, wherein at least one of the stomach contacting surfaces include structure for permitting fluid flow (Fig 3).

**27.** The device according to claim 22, wherein the front side member, connector, and backside member are integral (Fig 3).

**28.** The device according to claim 22, wherein the backside member and the connector are integral (Fig 3).

**32.** The device according to claim 22, wherein the front side member and the backside member include an aperture through which the front side member and the backside

member can be sutured to the stomach (Fig 4).

**33.** A non-invasive stomach stricture device, comprising: a front side member (Fig 3 Item 11); a backside member (Fig 3); a connector connecting the front side member to the backside member (Fig 3), the connector dimensioned to space the front side member from the backside member such that the device can be positioned over the stomach of a patient with the front side member over a front side of the stomach and the backside member positioned over the backside of the stomach, and the stomach will be constricted between the front side member and the backside member.

**34.** The device according to claim 33, wherein the connector and the backside member are integral (Fig 3).

**35.** The device according to claim 33, wherein the connector determines the distance between the front side member and the backside member (Fig 3).

**36.** The device according to claim 33, further comprising a positioning member for positioning the stomach stricture device on the stomach of a patient (Fig 4 Item 40).

**38.** The device according to claim 36, wherein the positioning member is adjustable relative to the front side member and the backside member (the Examiner considers the positioning member to be adjustable).

**41.** The device according to claim 33, wherein the front side member is separable from the backside member for allowing the device to be removed from a patient (the Examiner considers the members to be separable).

**42.** The device according to claim 33, wherein the device is dimensioned for positioning adjacent to the trachea side of the upper quadrant of a human stomach to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material (Fig 4).

**43.** The device according to claim 33, wherein the device is dimensioned for positioning adjacent to the upper quadrant of a human stomach, substantially perpendicular to the esophagus, to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material (Fig 4).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 22-26, 28-34, and 36-43** are rejected under 35 U.S.C. 102(b) as being anticipated by Hopkins (US 4,458,681).

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Hopkins discloses:

**22.** A non-invasive stomach stricture device, comprising: a front side member (Fig 1 Item 10); a backside member (Fig 1 Item 12); a connector (Fig 1 see marked drawing Item 1 following this rejection) for coupling the front side member to the backside member to form a clamp, wherein the clamp is designed to clamp a stomach.

**23.** The device according to claim 22, wherein the clamp is designed to have a size and shape suitable for fitting adjacent to the trachea side of the upper quadrant of a stomach for regulating nutrient absorption and caloric intake by reducing the capacity of the stomach (Fig 8).

**24.** The device according to claim 22, wherein the backside member and the front side member include stomach contacting surfaces, the stomach contacting surfaces being free of piercing projections (Fig 1 Items 10 and 12).

**25.** The device according to claim 24, wherein at least one of the stomach contacting surfaces include structure for permitting fluid flow (Fig 1).

**26.** The device according to claim 22, further comprising: a positioning member for coupling to the front side member and the backside member to form a clamping assembly (Fig 1 Item 22 on the right side of the figure).

**28.** The device according to claim 22, wherein the backside member and the connector are integral (Fig 1 Item 15).

**29.** The device according to claim 22, wherein the connector comprises a slot adapted to receive the front side member so that the front side member can be coupled to the backside member to form a clamp (Fig 1 Item 15).

**30.** The device according to claim 26, wherein the backside member and the front side member each comprise an anchoring slot, each anchoring slot adapted to receive an end of the positioning member (Fig 1 Items 14 and 15 on the right side of the figure).

**31.** The device according to claim 30, wherein each slot and the positioning member include corresponding engagement structure for coupling the positioning member to the front side member and the backside member (Fig 1 Items 14 and 15 and Item 22).

**32.** The device according to claim 22, wherein the front side member and the backside member include an aperture through which the front side member and the backside member can be sutured to the stomach (Fig 1 Items 14 and 15).

**33.** A non-invasive stomach stricture device, comprising: a front side member (Fig 1 Item 10); a backside member (Fig 1 Item 12); a connector connecting the front side



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member to the backside member (Fig 1 see marked drawing Item 1 following this rejection) the connector dimensioned to space the front side member from the backside member such that the device can be positioned over the stomach of a patient with the front side member over a front side of the stomach and the backside member positioned over the backside of the stomach, and the stomach will be constricted between the front side member and the backside member.

**34.** The device according to claim 33, wherein the connector and the backside member are integral (Fig 1 Item 12).

**36.** The device according to claim 33, further comprising a positioning member for positioning the stomach stricture device on the stomach of a patient (Fig 1 Item 22).

**37.** The device according to claim 36, wherein the positioning member couples to a portion of the front side member and to a portion of the backside member (Fig 1 Item 22).

**38.** The device according to claim 36, wherein the positioning member is adjustable relative to the front side member and the backside member (Fig 1).

**39.** The device according to claim 37, wherein the backside member and the front side member each comprise an anchoring slot for receiving an end of the positioning

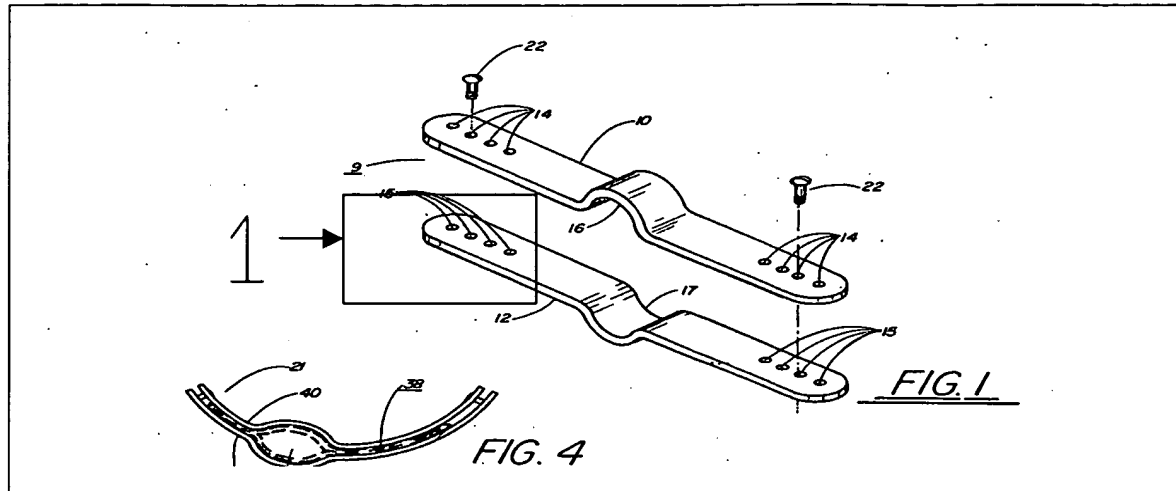
member (Fig 1 Items 14 and 15 right side of figure).

**40.** The device according to claim 39, wherein the positioning member comprises engagement structure for connecting with at least one corresponding engagement structure in at least one of the front side member and the backside member (Fig 1 Item 22).

**41.** The device according to claim 33, wherein the front side member is separable from the backside member for allowing the device to be removed from a patient (Fig 1).

**42.** The device according to claim 33, wherein the device is dimensioned for positioning adjacent to the trachea side of the upper quadrant of a human stomach to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material (Fig 8).

**43.** The device according to claim 33, wherein the device is dimensioned for positioning adjacent to the upper quadrant of a human stomach, substantially perpendicular to the esophagus, to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material (Fig 8).



### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
